

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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:
ENDO PHARMACEUTICALS, INC., :
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Plaintiff, : 13-CV-03288 (TPG)
:
- against - : **OPINION**
:
ROXANE LABORATORIES, INC., :
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Defendant. :
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Before the court is defendant's motion for leave to amend its answer to the complaint. Defendant seeks leave to plead three additional defenses to plaintiff's claims: (1) an affirmative defense of express license; (2) an affirmative defense of implied license; and (3) an affirmative defense of unclean hands. For the following reasons, defendant's motion is denied in part and granted in part.

Background

Plaintiff sells Opana® ER tablets which contain the painkiller oxymorphone. On May 15, 2013, plaintiff sued defendant claiming that defendant's plan to sell generic

oxymorphone tablets infringed on its patents numbered 7,851,122 (the “122 patent”), 8,329,216 (the “216 patent”), and 7,851,482 (the “482 patent”). Plaintiff sought a preliminary injunction to prevent defendant from marketing and offering the generic tablets. Defendant opposed the preliminary injunction, arguing that an earlier settlement in a case involving different patents, memorialized in a settlement and license agreement, gave it an express and implied license to sell the generic drugs. This court denied plaintiff’s motion for a preliminary injunction on estoppel grounds, reasoning that plaintiff, having agreed in the settlement and license agreement to allow defendant to use the patents at issue there, could not now assert new patents against defendant.

Plaintiff appealed to the United States Court of Appeals for the Federal Circuit. The Court of Appeals ruled for plaintiff and vacated the denial of its motion for a preliminary injunction. The Court of Appeals held that as a matter of law: (1) “Roxane’s express license arguments are meritless,” Endo Pharm. Inc. v. Actavis, Inc., 746 F.3d 1371, 1374 (Fed. Cir. 2014); and (2) “the district court erred . . . in finding legal estoppel in favor of . . . Roxane.” Id. at 1377.

Despite the Court of Appeals’ ruling, defendant filed a motion with this court for leave to amend its answer to the complaint to add express and implied license defenses with regard to the ’122 and ’216 patents, and also a defense of unclean hands.

Discussion

The Federal Rules of Civil Procedure allow a party to amend its pleading once as a matter of course within 21 of serving it. Fed. R. Civ. P. 15(a)(1). After 21 days have elapsed,

the party may amend its pleading “only with the opposing party’s written consent or the court’s leave.” Fed. R. Civ. P. 15(a)(2). The court should give such leave freely “when justice so requires.” Id. However, leave should not be granted where the amendment is unduly delayed or brought in bad faith, where it would prejudice the opposing party, or where it would be futile. Foman v. Davis, 371 U.S. 178, 182 (1962). An amendment to an answer will be futile if it fails to show at least colorable grounds for relief. S. Boston Mgmt. Corp. v. BP Products N. Am. Inc., No. 03-Civ.-6845(RBM), 2004 WL 2624891, at *2 (S.D.N.Y. Nov. 18, 2004).

1. Whether the Express License and Implied License Defenses are Futile.

At issue here is whether it would be futile for Roxane to assert defenses that have already been rejected by the Court of Appeals in the context of reviewing the denial of plaintiff’s motion for a preliminary injunction.

Under the law of the case doctrine, a trial court is bound by the appellate court’s previous ruling on an issue in the same case. United States v. Quintieri, 306 F.3d 1217, 1225 (2d Cir. 2002). This forecloses “relitigation of all issues previously . . . decided by the appellate court.” Id. Nonetheless, there are a number of reasons that may warrant departure from the law of the case, including “the discovery of new and different material evidence that was not presented in the prior action, or an intervening change of controlling legal authority, or when the prior decision is clearly incorrect and its preservation would work a manifest injustice.” Intergraph Corp. v. Intel Corp., 253 F.3d 695, 698 (Fed. Cir. 2001).

It is clear that a district court is not bound at trial by its prior conclusions made at the preliminary injunction stage. A court's purpose in granting a preliminary injunction is "merely to preserve the relative positions of the parties until a trial on the merits can be held." Univ. of Texas v. Camenisch, 451 U.S. 390, 395 (1981). Given the hasty nature of the proceedings on a motion for a preliminary injunction, a party is not required or expected to present its case in full. Id. Thus, the findings of fact and conclusions of law made by a court at the preliminary injunction stage are not binding on that court at trial. Id.

It is less clear, however, whether an appeals court's conclusions in reviewing the denial of a preliminary injunction have a preclusive effect on those same issues in the lower court. In *Lummus Co. v. Commonwealth Oil Refining Company, Inc.*, the Second Circuit considered whether the District Court for the Southern District of New York must give preclusive effect to a decision by the First Circuit holding that the plaintiff's claims were arbitrable under New York law. 297 F.2d 80, 81–84 (2d Cir. 1961). The Second Circuit reasoned that the "finality," or preclusive effect of the First Circuit's decision "turns upon such factors as the nature of the decision (i.e., that it was not avowedly tentative), the adequacy of the hearing, and the opportunity for review." Id. at 89.

Defendant argues that *Lummus* should not apply in this case, because it is a narrow exception to the general rule described in cases such as *Goodheart Clothing Co.* "that findings on a preliminary injunction are not binding going forward on the merits." Rep. Br. Roxane Supp. Mot. Amend. at 2 (citing Goodheart Clothing Co. v. Laura Goodman Enterprises, Inc., 962 F.2d 268, 274 (2d Cir. 1992)). However, the issue in *Goodheart* was whether a lower court's ruling on an issue at the preliminary injunction stage was binding on that same court.

Goodheart, 962 F.2d at 274. The issue was not whether an appeals courts' decision on preliminary issues would be binding on the lower court. Id.

There was nothing tentative about the Court of Appeals for the Federal Circuit's decision in this case. On appeal, defendant argued that it held an express license based on the earlier granted settlement and license agreement. Endo Pharm. Inc. v. Actavis, Inc., 746 F.3d 1371, 1373 (Fed. Cir. 2014). Pursuant to the agreement, plaintiff had granted defendant a license to practice three patents different from those at issue in this case. Id. at 1374. In interpreting the scope of this license, the Court of Appeals determined that "Roxane's express license arguments are meritless" because: (1) "there can be no dispute that the #122 and #216 patents are not continuations of any of the licensed patents," and (2) "there is no reasonable argument that the #122 and 216 patents claim priority to any of the licensed patents." Id. at 1374–75. The Court of Appeals held that defendant "do[es] not have an express license to practice any of the patents asserted in this litigation." Id. at 1376.

The Court of Appeals also rejected defendant's implied license argument. Defendant argued that under the Federal Circuit's decision in *TransCore, LP v. Electronic Transaction Consultants Corp.*, plaintiff should be equitably estopped from suing defendant for patent infringement when it had already granted different patent licenses in the earlier-settled litigation. The Federal Circuit rejected this reading of *TransCore*, reasoning that while *TransCore* does indeed preclude a patentee from selling a license and then seeking to "derogate from the right granted," its holding is narrow and limited to the licensed patent and continuations of the licensed patent. Id. at 1377–78 (citing TransCore, LP v. Electronic Transaction Consultants Corp., 563 F.3d 1271, 1279 (Fed. Cir. 2009)). Since defendant's

patents were clearly not continuations of the licensed patents, the Court of Appeals “reject[ed] [defendant’s] invitation to expand the implied license doctrine.” Id. at 1378.

Defendant challenges the adequacy of the hearing it received. Defendant claims that the proceedings regarding the preliminary injunction “were nowhere near the magnitude . . . of the proceedings in the preliminary-injunction cases where rulings have been deemed preclusive or binding.” Id. Moreover, defendant claims that the Court of Appeals only considered the plaintiff’s evidence of contract negotiations, and that its own evidence relating to those negotiations was not available in the appellate record. Id. It claims that new depositions call into doubt plaintiffs’ description of the contract negotiations, and that the Court of Appeals did not have this evidence when it reached its decision. Id.

These arguments overlook the fact that the Court of Appeals reached its decision by interpreting the settlement and license agreement as unambiguous as a matter of law. Endo, 746 F.3d at 1375. While the court did discuss contract negotiations in its opinion, it prefaced this discussion by stating “[t]he language of [of the settlement and license agreement] is clear on its face.” Id. Thus, the only evidence necessary to the Court of Appeals’ legal conclusions was the settlement and license agreement itself. See id. at 1379.

If this court were to allow defendant to amend its answer to include express and implied license defenses, this court would inevitably be required to duplicate the Court of Appeals’ efforts in interpreting the settlement and license agreement. If the agreement is, as both plaintiffs and defendants maintain, unambiguous, then this court would reach the same conclusion as the Court of Appeals. If this court were to find that the settlement agreement is ambiguous, its interpretation would squarely contradict the higher court’s determination

that the agreement is “clear on its face.” While this court could in certain circumstances revisit its own interpretation of a contract, it has no business doing the same for the Court of Appeals.

Thus, there are no colorable grounds to believe that defendant’s express and implied license defenses would afford them any relief. Defendant has failed to provide sufficient reasons for revisiting the issues already decided by the Court of Appeals for the Federal Circuit. Although the Federal Rules of Civil Procedure announce a liberal standard for amendment of the pleadings, they do not require amendment where doing so would be futile. Defendant’s motion to amend its answer should be denied with regard to the express and implied license defenses.

2. The Unclean Hands Defense.

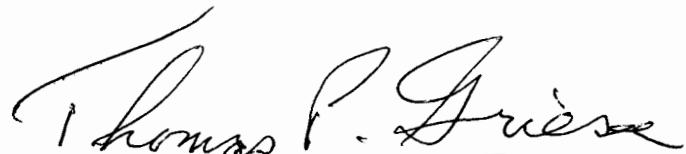
Defendant also seeks leave to amend its answer to assert a defense of unclean hands. Plaintiff does not oppose this amendment, and the Court of Appeals for the Federal Circuit did not consider it in its decision. Thus, defendant’s motion to amend its answer is granted with regard to the unclean hands defense.

Conclusion

For the reasons given above, defendant’s motion for leave to file a first amended answer is denied with regard to the express and implied license defenses. The motion is granted with regard to the defense of unclean hands.

This opinion resolves the motion listed as document number 65 in this case.

Dated: New York, New York
November 14, 2014



Thomas P. Griesa
Thomas P. Griesa
U.S. District Judge